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No. 10-1012

Supreme Court, U.S.
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In The

Supreme Court of the United States

HEATHER DUCASSE,

Petitioner,

v.

STATE OF MAINE,

Respondent.

On Petition For A Writ Of Certiorari To The Maine Supreme Judicial Court Sitting As The Law Court

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the admission of a certificate of compliance issued by the manufacturer of blood collection tubes used in blood alcohol kits stating that the chemical additives in the tubes "will not disturb the integrity of the blood sample relative to alcohol content" was a testimonial statement that violated Petitioner's right of confrontation under the Sixth Amendment as applied to the states by the Fourteenth Amendment to the United States Constitution.

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OPINION BELOW

The decision and order of the Maine Supreme Judicial Court sitting as the Law Court ("Maine Law Court") in *State v. Ducasse*, 8 A.3d 1252, 2010 ME 117 is reproduced in the Appendix at p. 1-9. The Kennebec County Superior Court for the State of Maine did not publish an opinion. Its pertinent rulings from the bench are reproduced in the Appendix at p. 19-30. The Judgment and Commitment is reproduced in the Appendix at p. 10-18.

JURISDICTION

The decision and order of the Maine Law Court affirming the Petitioner's conviction was entered on November 9, 2010. The Petitioner seeks review of the judgment by the highest state court in which a decision could be had and invokes this Court's jurisdiction under 28 U.S.C. § 1257(A).

CONSTITUTIONAL PROVISIONS INVOLVED

The Confrontation Clause of the Sixth Amendment to the United States Constitution provides in relevant part: "In all criminal prosecutions, the accused shall enjoy the right . . . to be confronted with the witnesses against him. . . ."

The Fourteenth Amendment to the United States Constitution provides in relevant part:

> All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

STATEMENT OF THE CASE

The Petitioner, Heather Ducasse, was indicted in the Kennebec County Superior Court on the charges of Manslaughter, a violation of 17-A M.R.S.A. § 203, and Aggravated Operating Under the Influence, a violation of 29-A M.R.S.A. § 2411. The Kennebec County Superior Court conducted a jury trial, which resulted in a guilty verdict on all counts. A timely Notice of Appeal was filed on March 3, 2010 and the Kennebec County Superior Court's file was transmitted to the Maine Law Court on March 30, 2010. Oral Argument was held before the Maine Law Court on October 5, 2010 and the Maine Law Court issued a decision affirming the convictions on November 9, 2010.

On July 11, 2008, Petitioner and the driver of a second motor vehicle were involved in a head-on collision. The driver of the other vehicle died as a result of that collision. Following the accident, Petitioner did not show any signs of intoxication other than the

smell of alcohol on her breath and glassy eyes, which were consistent with her crying according to the investigating officer.

Petitioner, who was slightly injured, was taken to a local hospital. A blood sample was taken from Petitioner approximately two hours after the accident. The blood sample was tested four days later and the Petitioner's blood-alcohol level was reported to be 0.19%. At trial, the Petitioner raised an issue concerning the possibility the blood alcohol sample was contaminated between the drawing and testing of the Petitioner's blood. The State's expert chemist testified that he did not know the type or amount of chemical additives in the blood test kit, and did not offer any testimony on the effect of the chemical additives on the blood alcohol test.

At trial, the Petitioner asserted the blood alcohol test result was inaccurate and inconsistent with the lack of signs of intoxication following the accident. In order to establish that the test was reliable and accurate, the State introduced, over Petitioner's contemporaneous objection, a certificate of compliance ("certificate") from the blood test kit manufacturer, which set forth the amounts of chemical additives in each test tube, that the tubes are manufactured specifically for blood-alcohol determination, and that the chemicals added "will not disturb the integrity of the blood sample relative to the alcohol content." The certificate is reproduced in the Appendix at p. 31.

At trial, this fact was introduced to address the Petitioner's defense that the blood alcohol test result

was inaccurate. The trial court concluded that the statement in the certificate was not "testimonial" under the Confrontation Clause and admitted the certificate.

REASONS FOR GRANTING THE PETITION

I. This Court should grant the petition for writ of *certiorari* to resolve the conflict between the Maine Law Court's decision and the majority of other decisions addressing the definition of "testimonial" statements under the Confrontation Clause.

This Court recently granted a petition for a writ of *certiorari* to resolve the divide among State high courts and federal courts of appeal on the question whether the Confrontation Clause permits the prosecution to introduce testimonial statements of a non-testifying forensic analyst through the in-court testimony of a person who did not perform or observe the laboratory test. *Bullcoming v. New Mexico*, 226 P.3d 1 (2010), *cert. granted*, 131 S.Ct. 62. The question presented in *Bullcoming* also implicates the constitutional distinction between "non-testimonial" data relied upon by an expert witness to reach a "testimonial" expert conclusion under the Confrontation Clause. *Ducasse v. Maine* presents this issue more clearly and directly than *Bullcoming*.

In *Crawford v. Washington,* 541 U.S. 36 (2004), this Court held that the prosecution may not introduce "testimonial" hearsay against a criminal defendant

unless the defendant has had an opportunity to cross-examine the declarant or unless the declarant is unavailable and the defendant has an opportunity for cross-examination. *Id.* at 54, 68. In *Crawford,* this Court defined testimony as "typically [a] solemn declaration or affirmation made for the purpose of establishing or proving some fact." 541 U.S. at 51 (quotation marks omitted). However, the definition of "testimonial" evidence was left to later cases.

In *Davis v. Washington*, 547 U.S. 813, 821-22 (2005), this Court held that statements "are testimonial when the circumstances objectively indicate that . . . the primary purpose of the interrogation is to establish or prove past events potentially relevant to later criminal prosecution." *Id.* at 822. In *Melendez-Diaz v. Massachusetts*, 557 U.S. ___, 129 S.Ct. 2527 (2009), this Court provided further guidance in holding that forensic laboratory reports are testimonial evidence. *Id.* at 2532.

In *Ducasse v. Maine*, the question presented is whether a statement that chemical additives "will not disturb the integrity of the blood sample relative to the alcohol content" constitutes a testimonial statement under the Confrontation Clause.[1] The Maine Law Court's decision conflicts with decisions of other

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[1] The Petitioner concedes that statements of the amount of chemical additives is non-testimonial, and only challenges the introduction of the expert conclusion that these chemical additives "will not disturb the integrity of the blood sample relative to the alcohol content."

state high courts and courts of appeals decisions, which draw a distinction between "non-testimonial" data that forms the basis for an expert opinion, and "testimonial" opinions derived from a review of that data.

This statement of opinion in the present case is "beyond common knowledge so that an untrained juror will not be able to determine it intelligently." Me.R.Evid. 702; *see also* Fed.R.Evid. 702. At trial, this opinion was proffered to establish an important fact at trial on which the State's expert chemist was not qualified to testify; namely, that the chemical additives could not have affected the blood test results. The State did not offer any witness testimony on this issue.

In *United States v. Washington*, 498 F.3d 225, 231 (4th Cir. 2007), *cert. denied*, 129 S.Ct. 2856 (2009), the Fourth Circuit examined the distinction between raw data and an expert's conclusions. In *Washington*, the court held that raw data print-outs are non-testimonial because they are "statements of the machines themselves, not their operators." *Id.* However, the Fourth Circuit did note that the Government called an expert toxicologist to offer opinion testimony based upon the data print-outs and test results. *Id.* at 228. In other words, the data that was the premise for the toxicologist's opinion was not "testimonial," but the toxicologist's opinions drawn from that data were "testimonial." *Id.* at 231-32. The defendant's right of confrontation was satisfied by the toxicologist's appearance at trial. *Id.*

The Seventh Circuit reached the same conclusion in *United States v. Moon*, 512 F.3d 359 (7th Cir. 2008), *cert. denied*, 129 S.Ct. 40. In *Moon*, the Seventh Circuit held that "the Confrontation Clause does not forbid the use of raw data produced by scientific instruments, though the interpretation *of* those data may be testimonial." *Id.* at 362 (italics in original). Again, whether a statement was testimonial depended on whether it was non-testimonial raw data relied upon by an expert or a testimonial opinion rendered by the expert.

State high courts that have addressed this distinction have reached the same conclusion as the Fourth Circuit and Seventh Circuit. In *State v. O'Maley*, 932 A.2d 1, 14 (N.H. 2007), *cert. denied*, 129 S.Ct. 2856 (2009), the New Hampshire Supreme Court held that the results generated from a blood test were non-testimonial raw data. However, conclusions drawn from that data were testimonial and the Confrontation Clause was satisfied by the trial testimony of an expert witness on that issue. *Id.*

In *State v. Appleby*, 221 P.3d 525, 551-52 (2009), the Kansas Supreme Court noted the distinction between non-testimonial data that forms the basis of an expert's opinion and a testimonial expert opinion. The Kansas court stated:

> More generally, several courts have reasoned that the Confrontation Clause is not violated if materials that form the basis of an expert's opinion are not submitted for the truth of their contents but are examined to assess the

> weight of the expert's opinion. *E.g.*, *United States v. Lombardozzi*, 491 F.3d 61, 73 (2d Cir. 2007); *United States v. Henry*, 472 F.3d 910, 914 (D.C. Cir. 2007); *United States v. Adams*, 189 Fed.Appx. 120, 124, 2006 WL 1888737 (3d Cir. 2006) (unpublished opinion); *United States v. Stone*, 222 F.R.D. 334, 339 (E.D. Tenn. 2004); *People v. Sisneros*, 174 Cal.App.4th 142, 153-54, 94 Cal.Rptr.3d 98 (2009); *State v. Lewis*, 235 S.W.3d 136, 151 (Tenn. 2007); see Note, *Testimonial Hearsay as the Basis for Expert Opinion: The Intersection of the Confrontation Clause and Federal Rule of Evidence 703 after Crawford v. Washington*, 55 Hastings L.J. 1539, 1540 (2004).

Id. at 552.

The Kansas Supreme Court succinctly explained that:

> [The raw data] were the accepted sources of information generally relied on by DNA experts. Based on this scientific data – which by itself is nontestimonial – the experts in this case developed their personal opinions. These experts were available for cross-examination and their opinions could be tested by inquiry into their knowledge or lack of knowledge regarding the data that formed the basis for their opinion. Consequently, the right to confront the witnesses was made available to [the defendant].

Id. (internal citations omitted).

The Maine Law Court's decision stands in stark contrast to the decisions of other state high courts and courts of appeal. This Court should grant the petition for writ of *certiorari* to resolve this issue in light of its prior jurisprudence, grant of a writ of *certiorari* in *Bullcoming v. New Mexico*, 226 P.3d 1 (2010), *cert. granted*, 131 S.Ct. 62, and the recent *per curiam* decision in *Briscoe v. Virginia*, 559 U.S. ___ (2011) (Docket No. 07-11191).

II. The Maine Law Court's decision in *Ducasse v. Maine* was incorrectly decided.

The Maine Law Court's decision conflicts with decisions from other state high courts and courts of appeals because it improperly lumps together raw data and the expert conclusions based on that data in the same "non-testimonial" category. The fundamental difference between raw data (amount and type of chemical additives) and an expert conclusion (effect of chemical additives) is that the former are merely a premise of the latter, and usually lack evidentiary significance when considered in isolation outside an explanatory expert opinion. *See* Kenneth S. Broun, 1 *McCormick on Evidence* 72 (6th ed. 2006). In other words, the data or observations that comprise a premise of an opinion will be meaningless to a juror without the expert's explanatory conclusion.

In *Ducasse v. Maine*, the amount and type of chemical additives are not "testimonial" and mean little to a jury. However, the expert conclusion that

the chemical additives "will not disturb the integrity of the blood sample relative to alcohol content," based on the amount and type of chemical additives and the application of scientific principles, is testimonial evidence intended to establish an important fact at trial. This was especially an important fact at this trial due to the handling of the blood sample during the four-day period between the blood sample being drawn and tested.

The distinction between raw data and expert conclusions is not limited to blood alcohol evidence. For example, an electropherogram DNA analysis is "a graph that displays a series of different-colored peaks of different heights." *Roberts v. United States,* 916 A.2d 922, 927 (D.C. Ct. App. 2007). This graph merely reports measurements and would have virtually no evidentiary value to a trier of fact without testimonial evidence. Expert testimony interpreting the data and expert testimony on the accuracy of the test (rarity statistic) is relevant to a trier of fact in determining that there is link from a DNA sample and a known individual. To determine whether a match exists, an analyst must determine and consider the accuracy and reliability of the test. Whether the test is accurate and reliable is key opinion testimony. *E.g., McDaniel v. Brown,* ___ U.S. ___, 130 S.Ct. 665, 668 (2010). Expert opinion testimony on the rarity statistic is critical to the factfinder's assessment of whether the profile is so infrequent that the DNA match becomes compelling identification evidence. *See United*

States v. Morrow, 374 F. Supp. 2d 51, 63 (D.D.C. 2005).

In providing a rarity statistic for a DNA test, the analyst must rely on many out-of-court statements of other persons: researchers who compile and report population databases used to determine allele frequencies; mathematicians and geneticists who construct the formulae used to convert allele frequencies into profile frequencies; and computer programmers who write the software used by analysts to apply published data and formulae to instrument output in a laboratory. John M. Butler, *Fundamentals of Forensic DNA Typing* 229-49 (2009). Similar to *Ducasse v. Maine*, the premise for the opinion (amount and type of chemicals) is not testimonial, but the conclusion that a DNA match exists or that the chemicals "will not disturb the integrity of the blood sample relative to the alcohol content" under real-life, field conditions is testimonial evidence.

In its decision, the Maine Law Court wrongly decided this issue because it did not follow decisions from other state high courts and courts of appeals. In the present case, the statement of opinion that the chemical additives "will not disturb the integrity of the blood sample relative to the alcohol content" constitutes a testimonial statement under the Confrontation Clause of the Sixth Amendment to the United States Constitution.

III. This case clearly presents an issue of Constitutional importance.

This case presents an excellent vehicle for resolving the split of authority over the question presented. The Petitioner clearly and unambiguously objected at trial, arguing that the introduction of the Certificate of Completion violated the Confrontation Clause, and this case comes to this Court on direct review. Finally, the Maine Law Court resolved this issue on the merits. If this Court concludes that petitioner's confrontation rights were violated, she would be entitled to a new trial.

IV. The admission of the certificate of compliance was not harmless error.

The State of Maine may argue that any violation of the Petitioner's rights under the Confrontation Clause was harmless error. An assessment of "whether there was sufficient evidence on which the petitioner could have been convicted without the evidence complained of" cannot establish harmless error. *Fahy v. Connecticut,* 375 U.S. 85, 86 (1963); *see also United States v. Lane,* 474 U.S. 438, 450 n.13 (1986) ("[T]he harmless-error inquiry is entirely distinct from a sufficiency-of-the-evidence inquiry.") (internal quotation marks and citation omitted). Rather, "the government must demonstrate beyond a reasonable doubt that the tainted evidence did not contribute to the conviction." *United States v. Alvarado-Valdez,* 521 F.3d 337, 342 (5th Cir. 2008); *accord Fields v. United States,* 952 A.2d 859, 867-68 (D.C. 2008); *see generally*

Chapman v. California, 386 U.S. 18 (1967) (emphasis added). In the present case, the certificate was important evidence and it cannot be said that the erroneous introduction of this testimonial evidence was harmless beyond a reasonable doubt.

CONCLUSION

The Court should grant the petition for a writ of *certiorari* and reverse the decision of the Maine Supreme Judicial Court Sitting as the Law Court.

Dated at Portland, Maine, this 7th of February, 2011.

Respectfully submitted,

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MAINE SUPREME JUDICIAL COURT
Reporter of Decisions
Decision: 2010 ME 117
Docket: Ken-10-159
Argued: October 5, 2010
Decided: November 9, 2010

Panel: SAUFLEY, C.J., and ALEXANDER, SILVER,* MEAD, *GORMAN*, and JABAR, JJ.

STATE OF MAINE

v.

HEATHER A. DUCASSE

GORMAN, J.

[¶1] Heather A. Ducasse appeals from a judgment of conviction for manslaughter (Class A), 17-A M.R.S. § 203(1)(A) (2009), and aggravated operating under the influence (Class B), 29-A M.R.S. § 2411(1-A)(A), (1-A)(D)(1-A), (5)(D-2) (2008), entered in the Superior Court (Kennebec County, *Mills, J.*) following a jury trial. Ducasse contends that the court violated her Sixth Amendment right to confront witnesses by admitting in evidence a certificate of compliance from the manufacturer of the blood collection tubes in the

* Although not available at oral argument, Justice Silver participated in this opinion. *See* M.R. App. P. 12(a) ("A qualified justice may participate in a decision even though not present at oral argument.").

blood-alcohol kit used to collect Ducasse's blood sample.[1] We disagree and affirm the judgment.

I. BACKGROUND

[¶2] "We review the evidence presented at trial in the light most favorable to the State." *State v. Murphy*, 2010 ME 28, ¶ 2, 991 A.2d 35, 36.

[¶3] On July 11, 2008, Ducasse and the driver of a second motor vehicle were involved in a head-on collision. The driver of the other vehicle died as a result of that collision. Ducasse, who was slightly injured, was taken to a local hospital. A blood sample taken from Ducasse there approximately two hours after the accident revealed that Ducasse's blood-alcohol level at that time was 0.19%. Ducasse was subsequently charged with manslaughter (Class A), 17-A M.R.S. § 203(1)(A), and operating under the influence (Class B), 29-A M.R.S. § 2411(1-A)(A), (1-A)(D)(1-A), (5)(D-2).[2] She pleaded not guilty to both charges.

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[1] Ducasse also contends that (1) the indictment was not sufficient to charge the Class B offense of operating under the influence, and (2) the court abused its discretion in admitting expert testimony on the speed of Ducasse's vehicle. These arguments are unpersuasive.

[2] Title 29-A M.R.S. § 2411 (2008) has since been amended, though those amendments are not relevant in the present case. P.L. 2009, ch. 447, §§ 37-42 (effective Sept. 12, 2009) (codified at 29-A M.R.S. § 2411 (2009)). Title 29-A M.R.S. § 2411(1-A)(A), (1-A)(D)(1-A), (5)(D-2) (2008) state that it is a Class B crime to

(Continued on following page)

[¶4] In order to establish that Ducasse had an elevated blood-alcohol level at the time of the accident, the State offered testimony from the officer who was present when the blood sample was taken from Ducasse and who later transported the sample to the State lab for testing; a "Certificate of Compliance" issued by BD Diagnostics, the manufacturer of the blood collection tubes used in blood-alcohol kits; and the testimony of the chemist who analyzed the blood sample.

[¶5] The certificate of compliance recites that manufacturing specifications require certain amounts of powdered additives in each tube, that the tubes are manufactured specifically for blood-alcohol determination, and that the chemicals added "will not disturb the integrity of the blood sample relative to the alcohol content." Ducasse objected to the admission of the certificate on the ground that its admission would violate her Sixth Amendment right to confront the witnesses against her. The trial court concluded that the statements in the certificate were nontestimonial and admitted the document.

[¶6] The State lab approves blood-alcohol kits like the one used in this case. The chemist explained that, before those kits are distributed to law enforcement agencies, the lab tests one kit out of every batch

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operate a motor vehicle "[w]hile under the influence of intoxicants" or "[w]hile having a blood-alcohol level of 0.08% or more," when the operator "[i]n fact causes the death of another person."

of one hundred for the presence of alcohol or other volatiles, and, based on the sample tested from Ducasse's batch, reported that the kit tested contained no alcohol or other volatiles. The chemist also testified that Ducasse's blood-alcohol kit was sealed when he received it. He described the contents of the blood-alcohol kit, and explained the procedure for testing a blood sample with a gas chromatograph. He testified that he had no personal knowledge of the amount of additives in the blood collection tubes, and acknowledged that the amount of additives could affect the reliability of the blood test. Finally, the chemist testified that he certified the result of the gas chromatograph test and that the result was a reliable and accurate measurement of the alcohol concentration in Ducasse's blood sample.

[¶7] The jury found Ducasse guilty of both charges. On the count of manslaughter, the court sentenced her to twelve years of imprisonment with all but six years suspended, and four years of probation. On the count of operating under the influence, the court sentenced her to four years of imprisonment, to run concurrently with the manslaughter sentence, a fine of $2100, and a ten-year license suspension. This appeal followed.

II. DISCUSSION

A. Confrontation Clause

[¶8] Ducasse contends that admission of the certificate violated her Sixth Amendment right to

confront witnesses because it contained testimonial statements regarding the reliability of the blood-alcohol test. The trial court's legal conclusion that the statements in the certificate were nontestimonial, and thus admissible, is reviewed de novo. *State v. Mitchell,* 2010 ME 73, ¶ 41, 4 A.3d 478, ___; *State v. Metzger,* 2010 ME 67, ¶ 13, 999 A.2d 947, 951-52.

[¶9] The Confrontation Clause of the Sixth Amendment, as applied to states through the Fourteenth Amendment, *Pointer v. Texas,* 380 U.S. 400, 403 (1965), provides that "[i]n all criminal prosecutions, the accused shall enjoy the right . . . to be confronted with the witnesses against him."[3] U.S. Const. amend. VI. This Clause bars the "admission of testimonial statements of a witness who did not appear at trial unless he was unavailable to testify, and the defendant had had a prior opportunity for cross-examination." *Crawford v. Washington,* 541 U.S. 36, 53-54 (2004).

[¶10] Only testimonial statements are subject to exclusion by the Confrontation Clause. *Davis v. Washington,* 547 U.S. 813, 821 (2006); *see State v. Rickett,* 2009 ME 22, ¶ 11, 967 A.2d 671, 675 ("Nontestimonial statements are not subject to Confrontation Clause

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[3] Similarly, the Maine Constitution guarantees that "[i]n all criminal prosecutions, the accused shall have a right to . . . be confronted by the witnesses against the accused." Me. Const. art. I, § 6. Ducasse does not contend that article I, section 6 of the Maine Constitution provides any greater protection than its federal counterpart.

restrictions."). In *Crawford,* the United States Supreme Court defined testimony as "typically [a] solemn declaration or affirmation made for the purpose of establishing or proving some fact." 541 U.S. at 51 (quotation marks omitted). The Court has also identified a "core class of testimonial statements":

> [*E*]*x parte* in-court testimony or its functional equivalent – that is, material such as affidavits, custodial examinations, prior testimony that the defendant was unable to cross-examine, or similar pretrial statements that declarants would reasonably expect to be used prosecutorially; extrajudicial statements . . . contained in formalized testimonial materials, such as affidavits, depositions, prior testimony, or confessions; statements that were made under circumstances which would lead an objective witness reasonably to believe that the statement would be available for use at a later trial.

Melendez-Diaz v. Massachusetts, 129 S. Ct. 2527, 2531 (2009) (quotation marks omitted); *accord Crawford,* 541 U.S. at 51-52.

[¶11] Recently, the Supreme Court held that the admission of certificates declaring that a forensic analysis had determined that substances found on a defendant were cocaine violated the defendant's right to be confronted with the witnesses against him. *Melendez-Diaz,* 129 S. Ct. at 2532. In holding that the certificates fell within the "core class of testimonial statements," the Court stated that the certificates

were "functionally identical to live, in-court testimony, doing precisely what a witness does on direct examination." *Id.* at 2532 (quotation marks omitted). The Court further reasoned that cross-examination would ensure accurate forensic analysis and "weed out" incompetent analysis, and that confrontation would not be useless "in testing analysts' honesty, proficiency, and methodology." *Id.* at 2536-38. The Court distinguished business records from the core class, however, stating that they are generally admissible absent confrontation "because – having been created for the administration of an entity's affairs and not for the purpose of establishing or proving some fact at trial they are not testimonial." *Id.* at 2538-40.

[¶12] Recently, we considered whether a certificate issued by the Secretary of State, which recited that notice of suspension had been sent to the defendant, violated his right to confront witnesses. *Murphy,* 2010 ME 28, ¶ 1, 991 A.2d at 36. We said: "Read expansively, *Melendez-Diaz* might be interpreted as extending the definition of testimony beyond sworn certificates addressing scientific analysis prepared for purposes of a criminal prosecution, to include sworn certificates that authenticate and summarize routine governmental records." *Id.* ¶ 19, 991 A.2d at 41. In determining that the certificate was admissible, we reasoned that it contained "neutral information" and did not involve expert analysis or contain "testimony" of the Secretary's personal knowledge. *Id.* ¶ 21, 991 A.2d at 42. We also noted

that the certificate was not "primarily maintained and employed for purposes of criminal prosecution," and concluded that "the crucible of cross-examination" had little practical benefit because "the data collected are not subject to any serious interpretation, judgment, or analysis." *Id.* ¶¶ 22-24, 991 A.2d at 42-43. Finally, we reasoned that the certificate was reliable as a public record. *Id.* ¶ 25, 991 A.2d at 43-44.

[¶13] Like the Secretary of State's certificate in *Murphy,* the certificate of compliance is not a "sworn certificate[ ] addressing scientific analysis prepared for purposes of a criminal prosecution." It is a manufacturer's certificate addressing its compliance with manufacturing specifications. Because the certificate does not report the results of a scientific analysis, cross-examination would have little or no practical benefit. Similarly, confrontation would not ensure accurate forensic analysis, "weed out" incompetent analysis, or provide defendants with an opportunity to explore the analysts' methodologies because the certificate does not report any analysis. Unlike the certificates in *Melendez-Diaz,* the certificate of compliance is a business record; it was "created for the administration of an entity's affairs and not for the purpose of establishing or proving some fact at trial." For these reasons, we conclude that the statements in the certificate are not testimonial, and that admission of the certificate did not violate Ducasse's Sixth Amendment right to confrontation.

The entry is:

Judgment affirmed.

Attorney for
Heather A. Ducasse:

Thomas S. Marjerison, Esq. (orally)
Norman, Hanson & DeTroy, LLC
415 Congress Street
PO Box 4600
Portland, Maine 04112-4600

Attorney for
the State of Maine:

Evert N. Fowle, District Attorney
Paul Rucha, Asst. Dist. Atty. (orally)
Prosecutorial District IV
Kennebec County Courthouse
95 State Street
Augusta, Maine 04330

Kennebec County Superior Court docket number CR-2008-812
FOR CLERK REFERENCE ONLY

STATE OF MAINE
SUPERIOR COURT

JUDGMENT AND COMMITMENT

Docket No.	County/location	Date	DOB
AUGSC-CR-2008-00812	KENNEBEC, ss.	02/18/2010	09/16/1978

State of Maine
v.
HEATHER A DUCASSE

Residence:
P.O. BOX 598
BELGRADE LAKES ME
04918

Offense charged:

Charged by: INDICTMENT
Charge: 1

MANSLAUGHTER

Class: A DOV: 07/11/2008 OBTN:
Seq #: 4248 Title: 17-A / 203 / 1/ A
Plea: NOT GUILTY

Offense convicted:

MANSLAUGHTER

Class: A DOV: 07/11/2008 OBTN:
Seq #: 4248 Title: 17-A / 203 / 1 / A
Charge: 1
PLEA: NOT GUILTY
FNDG: GUILTY
VRDT: GUILTY

IT IS ADJUDGED THAT THE DEFENDANT IS GUILTY OF THE OFFENSE AS SHOWN ABOVE AND CONVICTED. IT IS ADJUDGED THAT THE DEFENDANT BE HEREBY COMMITTED TO THE SHERIFF OF THE WITHIN NAMED COUNTY OR

AUTHORIZED REPRESENTATIVE WHO SHALL WITHOUT NEEDLESS DELAY REMOVE THE DEFENDANT TO:

The custody of DEPARTMENT OF CORRECTIONS, to be punished by imprisonment for a term of 12 year(s).

IT IS ORDERED THAT ALL BUT 6 YEAR(S) OF THE SENTENCE AS IT RELATES TO CONFINEMENT BE SUSPENDED AND THE DEFENDANT BE PLACED ON A PERIOD OF PROBATION FOR A TERM OF 4 YEAR(S) UPON CONDITIONS ATTACHED HERETO AND INCORPORATED BY REFERENCE HEREIN.

SAID PROBATION TO COMMENCE UPON COMPLETION OF THE UNSUSPENDED TERM OF IMPRISONMENT. IT IS ORDERED THAT THE DEFENDANT BE PLACED ON A PERIOD OF PROBATION FOR A TERM OF 4 year(s) UPON CONDITIONS ATTACHED HERETO AND INCORPORATED BY REFERENCE HEREIN. SAID PROBATION TO COMMENCE UPON COMPLETION OF THE UNSUSPENDED TERM OF IMPRISONMENT.

$ 25 VICTIMS COMPENSATION FUND
TOTAL DUE: $ 25.00

Execution/payment stayed to pay in full by 11/18/2016 or warrant to issue.

IF THE DEFENDANT HAS BEEN CONVICTED OF AN APPLICABLE OFFENSE LISTED IN 25 M.R.S.A. Sec.1574, THEN THE DEFENDANT SHALL SUBMIT TO HAVING A DNA SAMPLE DRAWN AT ANY TIME FOLLOWING COMMENCEMENT OF ANY TERM OF

IMPRISONMENT OR AT ANY TIME FOLLOWING COMMENCEMENT OF THE PROBATION PERIOD AS DIRECTED BY THE PROBATION OFFICER.

IT IS FURTHER ORDERED THAT THE CLERK DELIVER A CERTIFIED COPY OF THIS JUDGMENT AND COMMITMENT TO THE SHERIFF OF THE ABOVE NAMED COUNTY OR AUTHORIZED REPRESENTATIVE AND THAT THE COPY SERVE AS THE COMMITMENT OF THE DEFENDANT. REASONS FOR IMPOSING CONSECUTIVE SENTENCES ARE CONTAINED IN THE COURT RECORD OR IN ATTACHMENTS HERETO.

A TRUE COPY,
ATTEST: _____ s/ Nancy Mills
Clerk ~~Judge~~ / Justice

I UNDERSTAND THE SENTENCE IMPOSED HEREIN AND ACKNOWLEDGE RECEIPT OF A COPY OF THIS JUDGMENT AND COMMITMENT. I HEREBY ACKNOWLEDGE THAT THE DISCLOSURE OF MY SOCIAL SECURITY NUMBER ON THIS FORM IS MANDATORY UNDER 36 M.R.S.A. Sec. 5276-A. MY SOCIAL SECURITY NUMBER WILL BE USED TO FACILITATE THE COLLECTION OF MY FINE THAT HAS BEEN IMPOSED UPON ME IN THIS ACTION IF THAT FINE REMAINS UNPAID AS OF THE TIME I AM DUE A STATE OF MAINE INCOME TAX REFUND. MY SOCIAL SECURITY NUMBER ALSO MAY BE USED TO FACILITATE THE COLLECTION OF MONEY I MAY OWE THE STATE OF MAINE AS A RESULT OF HAVING HAD

AN ATTORNEY APPOINTED TO REPRESENT ME. COLLECTION OF ANY FINE OR REIMBURSEMENT OF MONEY WHICH I OWE TO THE STATE OF MAINE WILL BE ACCOMPLISHED BY OFFSETTING MONEY I OWE TO THE STATE AGAINST MY STATE OF MAINE INCOME TAX REFUND.

Social Security Number _____ – _____ – _____

Date: _____ Defendant _____
Address _____
_____

RETURN

By virtue of the within JUDGMENT AND COMMITMENT I have this day delivered the within named Defendant to the _____
_____

Date: _____

Deputy _____

By virtue of this warrant, the within-named Defendant has been removed to and received at the _____ on this day.

Date: _____

_____
Authorized Officer/Supt., M.C.C./
Warden M.S.P.

CR-121 Rev 01/2007

STATE OF MAINE
SUPERIOR COURT

JUDGMENT AND COMMITMENT

Docket No.	County/location	Date	DOB
AUGSC-CR-2008-00812	KENNEBEC, ss.	02/18/2010	09/16/1978

State of Maine
v.
HEATHER A DUCASSE

Residence:
P.O. BOX 598
BELGRADE LAKES ME
04918

Offense charged:

Charged by: INDICTMENT
Charge: 2

OPERATING UNDER THE INFLUENCE – DEATH

Class: B DOV: 07/11/2008 OBTN:
Seq #: 11185 Title: 29-A / 2411 / 1-A / D / 1-A
Plea: NOT GUILTY

Offense convicted:

OPERATING UNDER THE INFLUENCE – DEATH
Charge: 2

Class: B DOV: 07/11/2008 OBTN:
Seq #: 11185 Title: 29-A / 2411 / 1-A / D / 1-A
Charge: 2
PLEA: NOT GUILTY
FNDG: GUILTY
VRDT: GUILTY

IT IS ADJUDGED THAT THE DEFENDANT IS GUILTY OF THE OFFENSE AS SHOWN ABOVE AND CONVICTED. IT IS ADJUDGED THAT THE DEFENDANT BE HEREBY COMMITTED TO THE

SHERIFF OF THE WITHIN NAMED COUNTY OR AUTHORIZED REPRESENTATIVE WHO SHALL WITHOUT NEEDLESS DELAY REMOVE THE DEFENDANT TO:

The custody of DEPARTMENT OF CORRECTIONS, to be punished by imprisonment for a term of 4 year(s).

The sentence to be served concurrently with AUGSCCR200800812 Charge:1

IT IS ORDERED THAT THE DEFENDANT FORFEIT AND PAY THE SUM OF $ 2,100.00 AS A FINE TO THE CLERK OF THE COURT, PLUS APPLICABLE SURCHARGES AND ASSESSMENTS.

10% GOVT OPERATION SURCHARGE FUND $ 210.00
$ 25 VICTIMS COMPENSATION FUND
100% GENERAL FUND $ 2100.00
$ 30 DEPARTMENT OF TRANSPORTATION FINES
1% COUNTY JAIL $ 21.00
5% GENERAL FUND ADDL 5% SURCHARGE $ 105.00
3% MAINE CRIMINAL JUSTICE ACADEMY 2006 $ 63.00
1% MSP COMPUTER CRIMES $ 21.00
TOTAL DUE: $ 2,575.00

Execution/payment stayed to pay in full by 11/18/2016 or warrant to issue.

IT IS ORDERED THAT THE DEFENDANT'S MOTOR VEHICLE OPERATOR'S LICENSE OR PERMIT TO OPERATE, RIGHT TO OPERATE A MOTOR VEHICLE AND RIGHT TO APPLY FOR AND OBTAIN A

LICENSE IS SUSPENDED FOR A PERIOD OF 10 YEAR(S) EFFECTIVE.

THE DEFENDANT'S RIGHT TO REGISTER A MOTOR VEHICLE IS SUSPENDED.

IF THE DEFENDANT HAS BEEN CONVICTED OF AN APPLICABLE OFFENSE LISTED IN 25 M.R.S.A. Sec.1574, THEN THE DEFENDANT SHALL SUBMIT TO HAVING A DNA SAMPLE DRAWN AT ANY TIME FOLLOWING COMMENCEMENT OF ANY TERM OF IMPRISONMENT OR AT ANY TIME FOLLOWING COMMENCEMENT OF THE PROBATION PERIOD AS DIRECTED BY THE PROBATION OFFICER.

IT IS FURTHER ORDERED THAT THE CLERK DELIVER A CERTIFIED COPY OF THIS JUDGMENT AND COMMITMENT TO THE SHERIFF OF THE ABOVE NAMED COUNTY OR AUTHORIZED REPRESENTATIVE AND THAT THE COPY SERVE AS THE COMMITMENT OF THE DEFENDANT. REASONS FOR IMPOSING CONSECUTIVE SENTENCES ARE CONTAINED IN THE COURT RECORD OR IN ATTACHMENTS HERETO.

A TRUE COPY,
ATTEST: _____ s/ Nancy Mills
Clerk ~~Judge~~ / Justice

I UNDERSTAND THE SENTENCE IMPOSED HEREIN AND ACKNOWLEDGE RECEIPT OF A COPY OF THIS JUDGMENT AND COMMITMENT. I HEREBY ACKNOWLEDGE THAT THE DISCLOSURE OF MY SOCIAL SECURITY NUMBER ON

THIS FORM IS MANDATORY UNDER 36 M.R.S.A. Sec. 5276-A. MY SOCIAL SECURITY NUMBER WILL BE USED TO FACILITATE THE COLLECTION OF MY FINE THAT HAS BEEN IMPOSED UPON ME IN THIS ACTION IF THAT FINE REMAINS UNPAID AS OF THE TIME I AM DUE A STATE OF MAINE INCOME TAX REFUND. MY SOCIAL SECURITY NUMBER ALSO MAY BE USED TO FACILITATE THE COLLECTION OF MONEY I MAY OWE THE STATE OF MAINE AS A RESULT OF HAVING HAD AN ATTORNEY APPOINTED TO REPRESENT ME. COLLECTION OF ANY FINE OR REIMBURSEMENT OF MONEY WHICH I OWE TO THE STATE OF MAINE WILL BE ACCOMPLISHED BY OFFSETTING MONEY I OWE TO THE STATE AGAINST MY STATE OF MAINE INCOME TAX REFUND.

Social Security Number _____ – _____ – _____

Date: _____ Defendant _____

Address _____

_____

RETURN

By virtue of the within JUDGMENT AND COMMITMENT I have this day delivered the within named Defendant to the _____

_____

Date: _____

Deputy _____

By virtue of this warrant, the within-named Defendant has been removed to and received at the _____ on this day.

Date: _____

_____
Authorized Officer/Supt., M.C.C./
Warden M.S.P.

CR-121 Rev 01/2007

STATE OF MAINE
KENNEBEC, ss.

SUPERIOR COURT
Criminal Action
Docket No. CR-08-12
Law No. KEN-10-159

THE STATE OF MAINE)
V.)
HEATHER DUCASSE,)
Defendant)

TRIAL PROCEEDINGS
(with jury)

BEFORE:

THE HONORABLE NANCY MILLS
JUSTICE OF THE SUPERIOR COURT

Kennebec County Courthouse
95 State Street
Augusta, Maine

January 26-29, 2010
8:07 A.M.

APPEARANCES:

FOR THE STATE: PAUL A. RUCHA, ESQ.
FOR THE DEFENDANT:
THOMAS S. MARJERISON ESQ.

JANETTE L. COOK
OFFICIAL COURT REPORTER

* * *

[580] chemistry.

Q. So how long have you been involved in doing blood testing?

A. About 10 years.

Q. Have you testified in the courts in the state of Maine regarding your blood alcohol analyses?

A. I have.

Q. Were you working on July 14th of 2008?

A. Yes, I was.

Q. And before we – I guess before we head in to July 14th, let's talk for a moment about blood kits in the State of Maine. Do you have a job or is there a job at the lab in regards to blood kits when they're purchased by the State of Maine?

A. When we receive new blood kits from the manufacturer, we take out some of them and test them both the blood tubes and the povidone-iodine swab for the presence of any alcohol or other volatiles.

Q. And specifically are you familiar with the lot that this blood kit came from?

A. Yes.

Q. And do you know who checked to check the validity, if you will, of the blood kits?

[581] A. Yes, that was me.

Q. And when you say you checked them, once again, can you tell us what it is you actually have to do?

A. Yup, I take the – both blood tubes out of the new kit and I take out the iodine swab, I open one of the tubes and I open the swab and I squeeze as much liquid as I can get out of the iodine swab into one of the tubes. I then add a milliliter of deionized water into that tube and I mix it. I then add another milliliter of water to the other – the second tube and mix that. And I pour the contents of the first tube in to the second tube. So now I have 2 milliliters of water plus the iodine swab solution. And I take a milliliter of that and prepare a vial for the instrument that we do alcohol testing on and I run it on that instrument to see if there is any alcohol present.

Q. And in regards to the blood kit, or at least the sample from the blood kit we're doing here today, did you see any signs of alcohol - or ethanol?

A. I did not.

[582] Q. I'm going to show you what's been marked for identification as State's Exhibit No. 27 and ask you to take a look at that and tell me do you recognize that document?

A. Yes, I do.

Q. And did you get that document for me?

A. I did.

Q. And can you describe – or put on the record what it is?

A. This is a certificate of compliance from the manufacturer, BD Diagnostics, the manufacturer of the blood tubes in our alcohol kits.

MR. MARJERISON: Objection. Could we go to sidebar?

THE COURT: All right.

(THE FOLLOWING BENCH CONFERENCE TOOK PLACE OUT OF THE HEARING OF THE JURY.)

MR. MARJERISON: The same objection as before. I didn't realize that was the certificate of compliance. I think its hearsay for the reasons I stated previously on Melendez v Massachusetts. He's identified it but he can't go further. He can identify it. It's technically hearsay, but I just didn't want to interrupt him, draw attention.

[583] MR. RUCHA: Your Honor, the state's intention is to put in the certificate in order to comply with State versus Brewer. I think, Your Honor, Melendez requires that if there's a certificate of some type of an analysis, this is not an analysis. This is basically a manufacturer who creates something, that says this is what's in the kit.

And I understand counsel's argument regarding the expiration date, which is also under the certificate. I think the first issue, Your Honor, we have to

look at is does it meet – does it meet an exception in the hearsay, and I have heard from counsel that he is objecting to it for that ground, I think his objection is it's, hearsay, and he's trying to argue that it's Melendez. I think, Your Honor, that when you read that document, it's clearly what was anticipated in regards to what is a business record. It seems pointless, there's no testimony in that circumstance, what they're saying is we created this kit and this is what's in it.

MR. MARJERISON: It is hearsay, Your Honor. What he's arguing is it's hearsay but it [584] falls within an exception. The confrontation clause, the Supreme Court decided Melendez versus Massachusetts, requires a witness subject to cross-examination to testify. It's trying to convey information otherwise, therefore it's testimonial and therefore it violates the confrontation clause.

THE COURT: And your argument now has expanded to the entire kit or just the expiration date?

MR. MARJERISON: The expiration date and the certificate.

THE COURT: No, but –

MR. MARJERISON: Not the entire kit, no, Your Honor.

THE COURT: So it's just the expiration date.

MR. MARJERISON: The expiration date and the certificate right now, which is 27, State's 27.

THE COURT: Okay. But you're not suggesting that you need an expert to testify about the tubes or –

MR. MARJERISON: I think the state takes – no, I don't think I have to, no. I'm [585] not.

THE COURT: All right. So – go ahead.

MR. RUCHA: As I – well, if counsel is basically –

MR. MARJERISON: I'm not stipulating to anything. I am not stipulating to anything, Your Honor. Counsel can decide to do what he wants to do. If you're asking me whether I think the result would still come in, yes, but subject to the fact that, you know, that they don't have anybody to testify about the sterile tubes and everything, which may in fact be some instruction in the statute.

THE COURT: That's what I'm asking you, are you challenging the tubes and everything in the kit?

MR. MARJERISON: Yes. But I think ultimately an expert can testify what the blood alcohol was that he tested.

THE COURT: Yeah. We've already discussed that.

MR. MARJERISON: But I agree, yes, I am challenging that.

THE COURT: So you're challenging everything in the kit, that the fact –

[586] MR. MARJERISON: Yes.

THE COURT: That it's alcohol free.

MR. MARJERISON: Yes.

THE COURT: Okay. Then we need to take a break, because I'm on about page four of Melendez and I need to read it.

MR. MARJERISON: Should we complete it to get him out of here? I'm happy to stipulate that it goes with this particular kit and everything. If you say this is – if this doesn't fall within Melendez, it's admissible, I agree.

THE COURT: So you're not worried about having someone who keeps the records –

MR. MARJERISON: No, no, it's only the fact whether it's –

THE COURT: Okay. Thank you. That might be good, if we could finish him today.

MR. RUCHA: No, I agree.

THE COURT: Okay. So this is marked – you – I just wrote it, it's 27.

MR. MARJERISON: Thank you, Your Honor.

MR. RUCHA: Thank you.

(THE FOLLOWING PROCEEDINGS TOOK PLACE IN FRONT OF THE JURY.)

[587] BY MR. RUCHA:

Q. Mr. Pierce, let's talk for a couple of minutes now in regards to the lab. Can you explain or tell the members of the jury how it is that blood kits or blood vials actually come to the lab?

A. Yes. Our samples are either sent in the mail, sometimes first class, sometimes certified mail, and occasionally by UPS or Fed Ex. They are sometimes delivered in person by the law enforcement agency who is submitting them. And some of the samples are picked up at a drop box at the Augusta PD. If we're not – if the lab is not open and somebody wants to drop a sample off, they can drop it off at the Augusta PD, where there is a locked drop box, and we normally would pick samples up there a couple times a week, usually Monday and Friday.

Q. Okay. And in regards to these samples coming by mail or being put in the drop box, are they refrigerated in any means?

A. The ones sent through the mail would not be refrigerated, and the once [sic] in the drop box would not be refrigerated.

Q. Can you walk us through – first of all, on July

* * *

[636] ON THURSDAY, JANUARY 28, 2010, AT 8:49 A.M.)

THE COURT: All right. Good morning.

MR. MARJERISON: Good morning, Your Honor.

MR. RUCHA: Good morning.

THE COURT: You may be seated. All right. I will print off the e-mail that I sent to counsel last night so that it can be part of the record, but I determined that the Melendez-Diaz case does not prohibit the state's – the admissibility of State's Exhibit 27 or 5A, based on the expiration date. All right. Is Mr. Pierce here?

MR. RUCHA: He is, Your Honor. I didn't know if you wanted to address any of the other discussions we had regarding the motions or –

THE COURT: I'm sorry?

MR. RUCHA: I didn't know if you wanted to address that motion.

THE COURT: No, we can do that. I'd prefer to do that either at a break or later, so that we do not keep the jury waiting.

MR. MARJERISON: Sure. And, Judge, I just want to put on the record our discussion in chambers, that I have agreed that – I've [637] stipulated that a witness would testify – provide a sufficient foundation for introduction of business records with respect to 27. I maintain my objection that I stated earlier. The purpose of that is simply so the witness from Nebraska doesn't have to come here and lay a foundation in a minute and a half.

THE COURT: Right. Thank you.

MR. MARJERISON: Thank you, Your Honor.

MR. RUCHA: Your Honor, does the Court still have 27?

THE COURT: I do.

MR. RUCHA: I need that.

THE COURT: Why don't you just take all of these, in case you need them again.

MR. RUCHA: Okay.

THE COURT: Thanks. All set?

MR. RUCHA: Yes, Your Honor.

MR. MARJERISON: Yes, Your Honor.

THE COURT: Okay. All set, Bud, thank you.

THE JUDICIAL MARSHAL: All rise for the jury.

(THE JURY ENTERED THE COURTROOM AT 8:51 A.M.)

[638] THE COURT: Good morning, ladies and gentlemen, welcome back, you may be seated. Mr. Rucha.

DIRECT EXAMINATION

BY MR. RUCHA:

Q. Mr. Pierce, yesterday we had some discussions regarding – first of all your work at the lab and the fact that you had done – I show you again State's Exhibit 27. Can you tell us again what that is?

A. Yes, this is a certificate of compliance or – for the blood alcohol collection tubes that are used in the blood kits in the State of Maine.

Q. And you testified yesterday that you test to make sure there's no alcohol in those vials or in that substances?

A. I do.

Q. Okay. And we talked about potassium oxalate and sodium fluoride.

A. Yes.

Q. And can you tell us again what the purpose of having those in the vials is for?

A. Yes, potassium oxalate is an anticoagulant, it keeps the blood from clotting in the tube, and sodium fluoride is an antibacterial, it keeps [639] microorganisms from growing in the tube.

MR. RUCHA: Your Honor, I would move admission of State's Exhibit 27.

MR. MARJERISON: Objection, for the reasons previously stated, Your Honor. Thank you.

THE COURT: Thank you. 27 is admitted over objection.

* * *

[LOGO]

BD Diagnostics
Preanalytical Systems
150 South 1st Avenue
Broken Bow NE 68822 US

CERTIFICATE OF COMPLIANCE

Product Name	:	TUBE GLU GC 16X100 10.0 PLBL GR NAF/KOX
Catalog Number	:	367001
Batch Number	:	6299548
Expiration Date	:	2008/11/30

CERTIFICATION OF COMPLIANCE

This material number is a (TUBE GLU GC 16x100 10.0 PLBL GR NAF/KOX) BD Diagnostics Preanalytical Systems Blood Collection Tube reorder #367001. Manufacturing specification for this tube requires the following amounts of powdered additives in each tube.

Potassium Oxalate	18.0mg. to 23.0mg. (Nominal 20.0mg.)
Sodium Fluoride	90.0mg. to 115.0mg. (Nominal 100.0mg.)

This tube is manufactured specifically for blood alcohol determination. The chemicals added to this tube will not disturb the integrity of the blood sample relative to the alcohol content.

Vacuum in the tube is set to draw 9.3mL to 10.7mL (Nominal 10.0mL). Using a specific gravity for blood

of 1.057 grams the following would be the minimum and maximum percent of additive to blood.

Potassium Oxalate	0.16% to 0.23% (Nominal 0.19%)
Sodium Fluoride	0.80% to 1.17% (Nominal 0.95%)

Sterility Claim:

All products which are labeled as either "Sterile" or "Sterile Interior" and released for sale by BD Diagnostics Preanalytical Systems are certified to be sterile as long as the product package or product is unopened and undamaged. For those products labeled "Sterile Interior" only the product interior is sterile.

Manufacturing Claim:

BD Diagnostics Preanalytical Systems products are manufactured in accordance with the medical device regulations (21CFR820) and comply with Medical Device Reporting (MDR). Regulations (21CFR803). All products and manufacturing facilities comply with FDA registration and listing requirements (21CFR807). The released products ratify [sic] BD Diagnostics Preanalytical Systems finished product specifications. The Broken Bow facility is also ISO 9001:2000, CMDCAS, and ISO 13485:2003 certified.

Broken Bow Quality Assurance
Release date: 2006/12/06
Name: PATRICIA R YARRINGTON

This certificate is produced and controlled electronically and is valid without handwritten signatures.

/s/ Linette Asay
Linette Asay, QA/RA Manager

Acknowledgement
State of Nebraska)
County of Custer)

On this day Before me, Denise Barnes Woodward, the undersigned officer, personally appeared, Linette Asay, known to me to be the person whose name is subscribed to this instrument and acknowledged that she executed the same for the purpose therein contained.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal.

/s/ Denise Barnes Woodward

[SEAL] DENISE BARNES WOODWARD
MY COMMISSION EXPIRES
February 28, 2009

Denise Barnes Woodward, Notary Public
My Commission Expires 02/28/2009